K090526

510(k) Summary

Prepared: September 1, 2009

DEC - 2 2009

1. Submitter:

Company Name	: E-WOO Technology Co., Ltd.
Company Address	: 1F, 4F, Yunmin Technotown, 473-4, Bora-dong, Giheung-gu, Yongin-si, Gyeonggi-do, 446-904, Korea
U.S. Agent Address	: 256 N. Sam Houston Pkwy E. #115 Houston, TX 77060
Contact person	: Vincent Lee
Phone Number	: (281)598-8139
Fax Number	: (281) 598-8150

2. Identification of the Device :

Reason for 510(k)	: New Model
Manufacturer	: E-WOO Technology Co., Ltd
Trade Name	: E-Woo Technology
Model Name	: EzSensor
Classification Name	: MQB, Solid State X-ray Imager
FDA 510(k) #	: K090526

3. Equivalent legally marketed device :

Manufacturer	: Schick Technologies, Inc.
Trade Name	: Schick
Model Name	: CDR
Classification Name	: MQB, Solid State X-Ray Imager
FDA 510(k) #	: K072134

4. Indications for Use (intended use):

Indicated for intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.

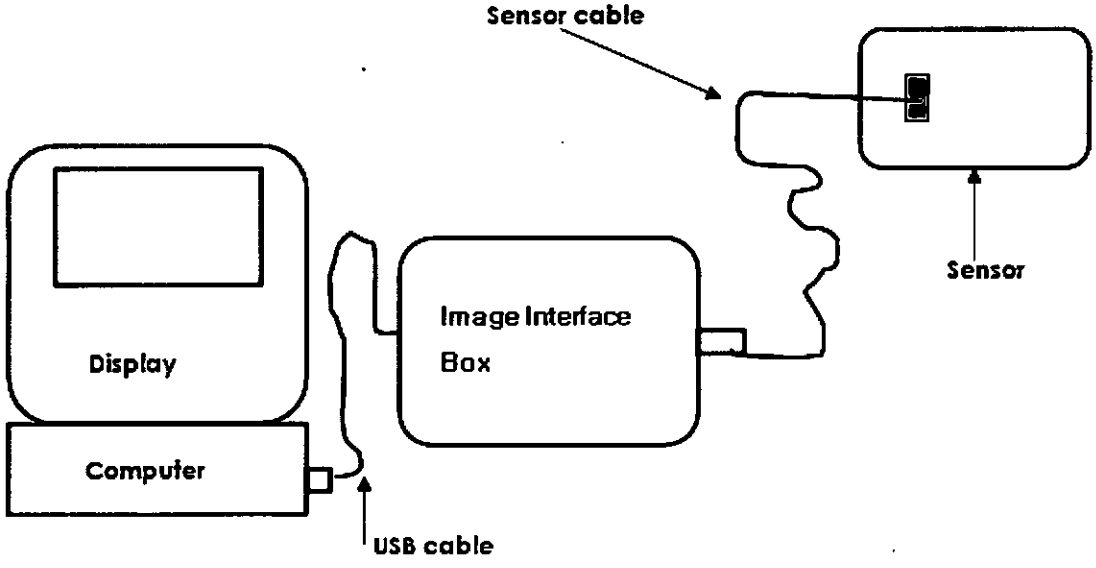
5. Description of the device :

The EzSensor is a solid state x-ray imager designed for dental radiographic applications.

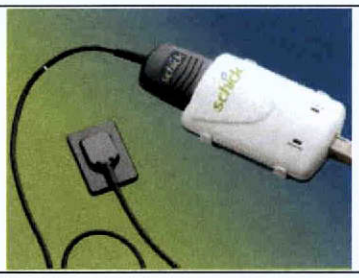
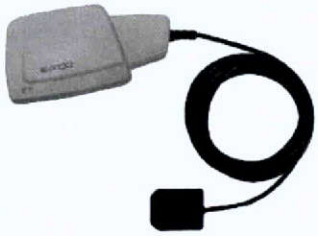
The EzSensor provides digital image capture for conventional film/screen radiographic dental examinations. The device is used to replace radiographic film/screen systems in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port.

The EzSensor configuration

- ✓ PC
- ✓ Image Interface Box (Read-out Box)
- ✓ X-ray sensor



6. Safety and Effectiveness, comparison to predicate device

	Predicate: CDR (K072134)	**Proposed: EzSensor (K090526)**
Feature		
Common/ Classification Name	Solid State X-Ray Imager	Solid State X-Ray Imager
Intended Use	The Computed Oral Radiology System is intended for intra-oral x-ray examinations and indicated for dental patients. It produces instant, digital, intra-oral x-ray images of a patient's mouth while reducing the necessary x-ray dosage.	EzSensor, Intra-oral Imaging System, is intended to collect dental x-ray photons and convert them into electronic impulses that may be stored, viewed, and manipulated for diagnostic use by dentists.
Device Description	-	The EzSensor is a solid state x-ray imager designed for dental radiographic applications. The EzSensor provides digital image capture for conventional film/screen radiographic dental examinations. The device is used to replace radiographic film/screen systems in general dental diagnostic procedures. The captured digital image is transferred to Personal Computer via USB interface port.
Sensor Dimensions (mm)	Size "0": 31x22 Size "1": 37x24 Size "2": 43x30	Size "1.0": 35.7x25.2 Size "1.5": 38.7x29.2
Sensor Thickness (mm)	5	4.9
Active Area (mm)	Size "0": 24x18 Size "1": 30x20 Size "2": 36x25.6	Size "1.0": 20.02x30.03 Size "1.5": 24.08x31.85
USB Module	Integrated USB 2.0 module	Integrated USB 2.0 module
Pixel Size (um)	0.40x0.40	0.35x0.35

7. Safety, EMC and Performance Data :

In all material respects the "EzSensor" is substantially equivalent to CDR of Schick Technologies, Inc. (K072134) Electrical, mechanical, environmental safety and performance testing according to standard EN/IEC 60601-1 was performed, and EMC testing was conducted in accordance with standard EN/IEC 60601-1-2(2001). All test results were satisfactory. Software testing and validation were done according to written test protocols established before testing was conducted. Test results were reviewed by designated technical professionals before software proceeded to release. Test results support the conclusion that actual device performance satisfies the design intent.

8. Testing information and Conclusion

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification E-WOO Technology Co., Ltd. concludes that The EzSensor is safe and effective and substantially equivalent to predicate devices as described herein.

9. E-WOO Technology Co., Ltd. will update and include in this summary any other information deemed seasonably necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

DEC - 2 2009

E-Woo Technology Co., Ltd.
% Mr. Vincent Lee
Regulatory Compliance Officer
E-Woo Technology USA, Inc.
256 North Sam Houston Pkwy E. #115
HOUSTON TX 77060

Re: K090526
Trade/Device Name: EzSensor
Regulation Number: 21 CFR 872.1800
Regulation Name: Extraoral source x-ray system
Regulatory Class: II
Product Code: MUH
Dated: October 8, 2009
Received: October 13, 2009

Dear Mr. Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number(if known): K 09 05 26

Device Name: EzSensor

Indications for Use:

The EzSensor is used to collect dental x-rays photons and convert them into electronic impulses that may be stored, viewed and manipulated for diagnostic use by dentists.

Prescription Use ✓ AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation(ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K090526